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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,777	06/20/2005	Allan Tanghoej	P70648US0	4949
69289	7590	05/11/2009		
COLOPLAST A/S Attention: Corporate Patents Holtedam 1 DK-3050 Humleback, DENMARK			EXAMINER SU, SUSAN SHAN	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 05/11/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,777	Applicant(s) TANGHOEJ, ALLAN	
	Examiner SUSAN SU	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-17, & 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 13, 2009 has been entered.

Status of Claims

Claims 1-21 are pending and examined on the merits. Claims 1, 9, & 10 are amended and Claim 21 is new.

Response to Arguments

2. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

3. Claim 1 is objected to because of the following informalities: typographical error. "to be used to insert allowing the oblong member into a urinary tract" should be changed to --to be used to insert the oblong member into a urinary tract--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3761

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-8, 9-10, 12-17, & 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Toledo et al. (US 6,248,100, "Toledo") in view of Frassica (US 6,379,334).

With regard to Claims 1, 14, & 20, Toledo teaches a device for opening a human bladder comprising:

an oblong member (422, see Fig. 26, it is solid since there are no openings in its wall) for opening the urethral sphincter and forming a distal end of the device, said oblong member being configured to open the urethral sphincter (when it is being advanced into the urethra it inherently opens the urethral sphincter) and drain fluid from the bladder into a urethra; and a guide member (424) fixedly coupled with the oblong member for manipulating the oblong member, at least a part of the guide member being made of an elastically deformable material in which said guide member is sufficiently rigid in a longitudinal direction to be used to insert

the oblong member into a urinary tract without buckling under longitudinal pressure (Col. 22 lines 1-4) associated with insertion.

Toledo also teaches that the guide member is connected to one end of the oblong member and is in substantially linear alignment therewith.

Toledo does not expressly teach that the guide member is flexible enough to be bent into a first configuration and then unfolding from said first configuration into a second configuration.

Frassica teaches that a guide member for a drainage catheter is bent into a first configuration (Fig. 10) and then unfolding into a second configuration (Fig. 7). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Toledo with Frassica so that it takes up less space and can be more easily handled prior to use.

With regard to Claims 2 & 3, Toledo also teaches that the guide member has a smaller cross-sectional area than the oblong member in the first and second configurations.

With regard to Claims 4-6, Toledo does not explicitly teach that the guide member is rolled and packed in the first configuration, nor does Toledo teach that the guide member in the first configuration is bent by an essentially elastic formation. However, since the guide member is flexible and can be bent (and also disclosed to be a metallic wire), it is also obvious that it can be rolled up (like how most cables used in everyday life are packaged for easier transport and better organization) and bent only to the extent that it is not permanently deformed (therefore allowing it to unfold when the

Art Unit: 3761

packaging material is removed). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Toledo and Frassica for the purpose of keeping the guide member in the more compact configuration for easier transport but not cause permanent deformation to the guide member so that it can be inserted into the urethra.

With regard to Claim 7, Toledo also teaches that the guide member is made of metal or from a polymer material or from a composite material (Col. 22 line 1).

With regard to Claim 8, Toledo also teaches that the guide member includes a gripping element (426, see Fig. 26).

With regard to Claim 13, Toledo does not expressly teach that the device is provided with a hydrophilic surface. However, Toledo teaches a stent (26) that is also meant for insertion into the urethra has been coated with a hydrophilic surface for easier insertion (Col. 6 lines 19-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Toledo by also coating the device as described in Claim 1 so that it will be easier to insert.

With regard to Claim 15, Toledo does not expressly teach that the oblong member allows for storage in a bent configuration. However, since the oblong member is made of the same material and also meant to be flexible enough for insertion into a urethra, it is obvious that the oblong member be made to allow for some bending (to minimize the tip of the oblong member from poking at the soft body tissues during insertion). It would have been obvious to one of ordinary skill in the art at the time of the

Art Unit: 3761

invention to modify Toledo so that the oblong member allows for storage in a bent configuration for easier packaging/handling.

With regard to Claims 16 & 17, Toledo also teaches a guiding device (414, see Fig. 31, all parts excluding 404 as shown in Fig. 26) with a compartment (e.g. interior of 406) for guiding drained urine, the guiding device being adapted to convey the oblong member from the compartment and into a urinary canal. Toledo also teaches a receptacle in fluid communication with the compartment of the guiding device (interior of 410, see Fig. 34).

With regard to Claim 19, Toledo also teaches that the receptacle is flexible (Col. 6 line 17). Since it is not defined in the instant Specification what receptacle material is flexible enough to allow for manipulation of the guide member through the receptacle wall, it is held that the plastic (which is used for 406/410 in Toledo) is flexible enough to allow manipulation of the guide member within.

With regard to Claim 21, Toledo and Frassica combine to teach the limitations that are previously presented in Claim 1. Furthermore, Frassica also teaches a channel disposed on an exterior of a device for urine drainage (channel is formed by the outer surface thread 33, see Fig. 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Toledo with Frassica for the purpose of easier insertion of the device with the added benefit of guiding urine out the urethra.

With regard to Claim 9, Toledo also teaches a slack tube (406 and 410) but does not disclose that the slack tube is less rigid than the oblong member. However, since the oblong member is used in introducing the device into the urethra, it is obvious to one

Art Unit: 3761

skilled in the art that it should be made more rigid so that it would not buckle during insertion while the slack tube is for draining urine and therefore should allow for more comfort while fitted inside the urethra. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Toledo and Frassica so that the slack tube can be made to provide better comfort during urine drainage.

With regard to Claim 12, Toledo also teaches that the slack tube includes a gripping element (413, Fig. 25) and allowing the user to grip the slack tube for removing the oblong member from a urinary canal (see Figs. 24 & 37D to see how the slack tube and the oblong member fit together).

Allowable Subject Matter

7. Claims 11 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. With regard to Claim 11, although varying the length of a working part of a device requires only ordinary skills in the art, but in the instant case, elongating the slack tube so that it is longer than the guide member would teach away from the prior art (Toledo) used in the rejection. Toledo teaches specifically that the gripping end of the guide member protrudes beyond the slack tube outside the body so that the user can pull the guide member out easily.

9. With regard to Claim 18, no prior art has been found to teach or suggest a sealing element to seal between the compartment and the urinary canal in addition to the limitations on which the instant claim are depended on. Based on the rejection of

Art Unit: 3761

Claim 16 (on which Claim 18 is depended), one skilled in the art would not want to seal between the compartment and the urinary canal because that may cause tissue damage to the luminal wall of the urinary canal.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/539,777

Page 9

Art Unit: 3761

/Susan Su/

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761